4742. Nu Youth tablets. (F. D. C. No. 36655. S. Nos. 40–225 L, 58–142 L.)

INFORMATION FILED: 7–28–55, S. Dist. Calif., against Frederic S. Weichman, t/a N-Y Distributing Co., Los Angeles, Calif.

SHIPPED: 1–15–54 and 1–20–54, from California to Arizona and Illinois.

LABEL IN PART: (Btl.) "Each tablet contains 5 mg. Methylandrostenediol suggested dosage. One tablet upon arising before breakfast and one tablet shortly before retiring. For adult males not for children or young adults Caution: Do not take more than dosage recommended. Continued use extending over six months to be avoided, except under supervision of a physician. Do not use in cases of cardiac and kidney disease, cancer of the prostate, defects of spermatogenesis, sterility or debilitation due to disease. Indications: Used in place of testosterone, methyltestosterone and testosterone propionate for its androgenic effect and as an anabolic agent * * * Nu Youth 60 Tablets."

ACCOMPANYING LABELING: Leaflets entitled "The Evidence" and undated letters addressed to "My Dear Friend" and signed by "Charles St. Regis" under the letterhead of N-Y Distributing Co.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the drug was a new, improved, safe sex hormone; that it could be used in place of testosterone, methyltestosterone, and testosterone propionate for its androgenic effect; and that it would be adequate and effective for providing renewed vigor, endurance, strength, and vitality in men over 40; for rejuvenating men by replenishing their deficient sex glands; for restoring masculine sex drive; for banishing mental fatigue; for boosting muscle power; for replenishing energy and endurance; for increasing mental alertness and ending irritability; for providing health, sexual aliveness, and emotional stability; for sex problems and impotency; for restoring waning physical and mental powers in men; for providing pep and vitality; and for providing the proper functioning and well-being of the human body; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling; 503 (b) (1)—the article was dispensed without a prescription therefor from a practitioner licensed by law to administer the drug; and 503 (b) (4)—the article was subject to 503 (b) (1), and at a time prior to dispensing, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 9–26–55. $200 fine.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

4743. Achromycin capsules. (F. D. C. No. 37701. S. No. 12–707 M.)

QUANTITY: 52 100-capsule btls. at West Orange, N. J.

SHIPPED: During January 1955, from Bronx, N. Y., by Al Getzoff, t/a Re Ly On Drug Co.

LABEL IN PART: (Btl.) "Stellar Drug Company Wholesale Druggists 32 West 15th Street New York 11, N. Y. (100) Achromycin Capsules 250 mg. repacked (Lederle) #4768 Nov. 1956."

LIBELED: 3–8–55, Dist. N. J.

CHARGE: 502 (e) (2)—the label of the article when shipped failed to bear the common or usual name of the active ingredient, tetracycline; 502 (f) (1)—the labeling of the article failed to bear the information required by regulations

exempting the drug from bearing adequate directions for use in its labeling; 502 (l)—the article was composed wholly or partly of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; and 503 (b) (4)—the article was subject to the provisions of 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 4–14–55. Default—delivered to the Food and Drug Administration.

4744. Achromycin capsules and terramycin capsules. (F. D. C. No. 37927. S. Nos. 21–805/6 M.)

QUANTITY: 1 300-capsule btl. of *Achromycin capsules* and 2 250-capsule btls. of *terramycin capsules* at Philadelphia, Pa.

SHIPPED: 8–4–54, from Franklin Square, Long Island, N. Y., by Economy Buying Service, Inc.

RESULTS OF INVESTIGATION: Analyses showed that the *Achromycin capsules* contained 250 milligrams of tetracycline hydrochloride per capsule and that the *terramycin capsules* contained 250 milligrams of oxytetracycline hydrochloride per capsule.

LIBELED: 4–7–55, E. Dist. Pa.

CHARGE: 502 (b) (1)—the labels of the articles when shipped failed to bear the name and place of business of the manufacturer, packer, or distributor; 502 (f) (1)—the labels of the articles failed to bear adequate directions for use; 503 (b) (4)—the articles were subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 502 (l)—the *Achromycin capsules* purported to be and were represented as a drug composed wholly or partly of a derivative of chlortetracycline, and the capsules were not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: 7–27–55. Default—destruction.

4745. Nasal hydrocortisone, nasal solution, and Aureomycin capsules. (F. D. C. No. 37954. S. Nos. 13–661/3 M.)

QUANTITY: 7 ½-oz. vials of *nasal hydrocortisone*, 7 ½-oz. vials of *nasal solution*, and 1 100-capsule btl. of *Aureomycin capsules*, at Philadelphia, Pa.

SHIPPED: During January 1955, from Franklin Square, Long Island, N. Y., by Carl H. Kaplan, t/a Economy Buying Service, Inc.

LABEL IN PART: (Vial) "'Vasocort' Hydrocortisone Nasal" and "Drilitol Nasal Solution"; (btl.) "100 * * * Lederle Aureomycin Hydrochloride Crystalline Capsules 250 mg."

RESULTS OF INVESTIGATION: The *Aureomycin capsules* were shipped in a bulk container and were placed by the shipper in the above-described bottle when he delivered the capsules to the consignee, who supplied the bottle.

Partial analyses disclosed that the *nasal hydrocortisone* contained hydrocortisone and Paredrine; that the *nasal solution* contained thenylpyramine hydrochloride, Paredrine, and polymyxin B; and that the *Aureomycin capsules* contained about 155 milligrams of chlortetracycline per capsule.

LIBELED: 4–29–55, E. Dist. Pa.; amended libel filed 6–2–55.

CHARGE: 501 (b)—the *Aureomycin capsules* purported to be and were represented as a drug, the name of which is recognized in the United States Pharma-